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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,821	07/16/2003	Vadim Kutsyy	CYTOP110	1277
22852	7590	01/27/2006	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			SKIBINSKY, ANNA	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/621,821	Applicant(s) KUTSYY ET AL.	
	Examiner Anna Skibinsky	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 15-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/8/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **Detailed Action**

#### *Response to Applicant's Election*

1. Applicant's election with traverse of Group II (claims 15-26) in the reply filed on December 19, 2005 is acknowledged. The traversal is on the ground(s) that the examination of Groups I and II would not be a serious burden. This is not found persuasive because Group I is drawn to a method, program product, and computing device for investigating a treatment applied to cells while Group II is a method for investigating a treatment applied to cells specifically with the use and manipulation of data captured from imaging the cells.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 19, 2005.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (US Patent No. 6611833, filed June 23, 1999) in view of Friend et al. (US Patent No. 6,801,856, filed December 23, 1998).

5. As in instant claim 15-17, Johnson teaches a database of "blueprints" of cellular tissue where statistical characteristics of tissue are collected after a population of tissue is profiled through imaging methods (col. 1, lines 45-56 and col. 2, lines 14-48). The tissues are profiled and a plurality of structural indices are generated (col. 3, lines 5-59 and col. 4, lines 45-67). The distribution of measured characteristics are calculated and stored for "normal" and "abnormal" tissue (col. 5, lines 27-52). The "normal" and "abnormal" tissue can then be accessed by a user who would like to compare his samples to the tissues in the database.

6. As recited in instant claims 15-17, the prior art of Johnson teaches the imaging of a population of cells, creating the on-target effect signature which is the characteristic for which an index is measured for "normal" tissue, and a side effect signature which is the characteristic of "abnormal" tissue that is either stored in the database or in the possession of the user (col. 21, lines 24-43). Comparisons can be made between the features of the "normal" and "abnormal tissue".

7. The prior art of Johnson does not teach exposing the tissue to a treatment (as recited in line 3 of instant claim 1) and evaluating a metric derived from an on-target signature and side effect signature to characterize the treatment (as recited in line 14 of instant claim 1).

8. Friend et al. teaches obtaining a response profile for a compound to determine if the compound exhibits an "ideal" vs. a "non-ideal" effect. The prior art of Johnson et al. involves treating cells with a drug to measure drug effectiveness and toxicity (col. 2, lines 42-62). The calculation of a similarity metric for comparing biological response profiles is also taught (col. 4, lines 27-38).

9. As in instant claims 19-21, Johnson teaches deriving an "on-target metric" and "side effect metric" in the form of indices of "normal", "abnormal", and user introduced tissue. The metrics are the index values referred to throughout the text which are calculated from the various signature characteristics determined from the imaging. For example cellular DNA and mRNA characteristics and indexes are discussed (col. 15, lines 9-44). The control group (as recited in instant claim 20) is either the "normal" or "abnormal" tissue data in the database accessed by the user (col. 21, lines 24-43). The imaging (as recited in instant claim 21) is taught for profiling the tissue specimens (col. 3, lines 25-35).

10. Johnson does not teach varying the doses of treatment (as in instant claim 19).

11. Friend et al. teaches building "consensus profiles" for response of cells to various drugs by exposing them to graded levels of the drugs (col. 6, lines 1-19).

12. Johnson teaches the measurement of qualitative data from cellular features determined from images. The data can be accessed by users to compare different states the tissue against the tissue in the database to determine if there has been a response which is "normal" or "abnormal". Though Johnson recites that the inventions can be used for drug development, he does not specifically recite varying the exposing

the cellular tissue to treatment (instant claim 18). Additionally, Johnson does not perform calculations in multivariate space (instant claims 22 and 23).

13. Friend et al. however does teach exposing cells to drug treatment, monitoring them for "ideal" and "non-idea" effects, and based on generated profiles identifies compounds with the desired activity (col. 6, lines 1-19 and col. 8, lines 19-51). Additionally, the calculation of metrics are specifically taught (col. 4, lines 27-38). The use of multivariate space is used to calculate the biological profiles (col. 12, lines 41-62). Data is clustered and the distances between the clusters is calculated (col. 20, lines 30-40).

14. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have implemented the invention of Johnson where images of "normal" and "abnormal" cell tissues are taken and the quantitative properties of cellular features are measured to form indices that can be accessed and used for comparison. One of skill in the art would have been motivated to use such a system of categorizing cellular data since image analysis can reveal data about cellular states. One of skill in the art would have had the further motivation to treat the cells with various doses of drug candidates and determine the responses with image analysis as taught by Friend. The classification of image data as taught by Johnson is not limited to tissue that is "normal" or "abnormal" and can be used to categorize and study the cellular expected or unexpected side effect response of cells when subjected to drug treatment. One of skill in the art would have had a reasonable expectation of success at using the imaging and measurement of quantitative characteristics of cells as taught by Johnson

on the drug candidate treated cells of Friend et al. The multivariate space calculations as taught by friend et al. could have also formed the indices of quantitative values forming the database in Johnson et al. Therefore, the invention as a whole would have been prima facie obvious, absent evidence to the contrary.

***Claim Rejections - 35 USC § 112***

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. Claims 24-26 recite the limitation "stimulus" are related to the characterizing of the side effect and on-target distance. There is insufficient antecedent basis for this limitation in the claim.

18. Claims 24-26 also recite a "side effect distance" and "on-target distance" which is vague and indefinite. It is unclear what these distances are measured in relation to. Please clarify the metes and bounds via clearer claim language.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

19. Claims 15-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

20. Claims 15-26 are drawn to methods which characterize a treatment applied to cells via imaging the cells, identifying signatures as a result of the treatment or lack thereof, and calculating metrics. These claims produce a result which does not meet the standard of being concrete, tangible and useful, as required.

Non-statutory inventions include descriptive material, and computer programs without computer-readable media. Currently the method claims recited by the applicant do not include a step with makes [for example, the result of] the method concrete, tangible, and useful. A step of displaying the data for a user or inputting initial data by a user into a computer is lacking.

21. The method steps at present are a manipulation of "data-in-space" and are therefore non-statutory.

22. The claims "must be for a practical application of the abstract idea, law of nature, or natural phenomenon. Diehr, 450 U.S. at 187, 209 USPQ at 8 ("application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."); Benson, 409 U.S. at 71, 175 USPQ at 676 (rejecting formula claim because it "has no substantial practical application").

23. To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways:

1) The claimed invention "transforms" an article or physical object to a different state or thing.

2) The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed in MPEP 2106, and See also:

[http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101\\_20051026.pdf](http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf)

24. Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data. Both types of "descriptive material" are nonstatutory when claimed as descriptive material per se. Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759. When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material, i.e., abstract ideas, stored in a computer-readable medium, in a computer, on an electromagnetic carrier signal does not make it statutory. See Diehr, 450 U.S. at 185-86, 209 USPQ at 8 (noting

that the claims for an algorithm in Benson were unpatentable as abstract ideas because “[t]he sole practical application of the algorithm was in connection with the programming of a general purpose computer.”). Such a result would exalt form over substance. In re Sarkar, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978).

(a) Functional Descriptive Material: “Data Structures” Representing Descriptive Material

25. Per Se or Computer Programs Representing Computer Listings Per Se  
Data structures not claimed as embodied in computer-readable media are descriptive material per se and are not statutory because they are not capable of causing functional change in the computer. See, e.g., Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory). Such claimed data structures do not define any structural and functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure’s functionality to be realized. In contrast, a claimed computer-readable medium encoded with a data structure defines structural and functional interrelationships between the data structure and the computer software and hardware components which permit the data structure’s functionality to be realized, and is thus statutory.

26. Similarly, computer programs claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical “things.” They are neither computer components nor statutory processes, as they are not “acts” being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed elements of a

computer which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See Lowry, 32 F.3d at 1583-84, 32 USPQ2d at 1035.

**(b) Nonfunctional Descriptive Material**

Nonfunctional descriptive material that does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. § 101. Certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, without any functional interrelationship is not a process, machine, manufacture or composition of matter. Nonfunctional descriptive material may be claimed in combination with other functional descriptive multi-media material on a computer-readable medium to provide the necessary functional and structural interrelationship to satisfy the requirements of 35 U.S.C. § 101.

[http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101\\_20051026.pdf](http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf)

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MARY K. ZEMAN  
PRIMARY EXAMINER

10/631  
1/23/06